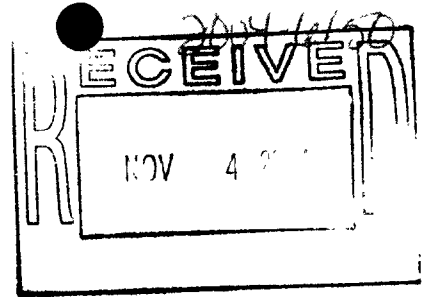




Center for  
Science in the  
Public  
Interest

nonprofit  
publisher of

**Nutrition Action Healthletter**



October 28, 2004

Acting Commissioner Lester Crawford, Ph.D., D.V.M.  
Food and Drug Administration  
5600 Fishers Lane, 14-71  
Rockville, MD 20857

Re: Misbranding of Single-serving Foods

Dear Dr. Crawford:

Obesity has become an issue of national importance to Americans. The dramatic increase in product serving sizes over the last decade, particularly the advent of super-sized soft drinks and large packages of baked goods and snacks, appears to have contributed to soaring obesity rates.

Consumers may be misled by labels that provide information for fractions of packages of foods, when those packages are typically consumed as a single serving. For example, the Nutrition Facts panel on a 20-ounce beverage states that the bottle contains 2.5 100-calorie servings. However, normally the entire bottle is consumed as a single serving, providing 250 calories.

The Center for Science in the Public Interest ("CSPI") is pleased that the Food and Drug Administration ("FDA") has designated modernizing serving-size regulations as one useful, if small, measure for fighting obesity. We specifically urge the FDA to:

(1) Take enforcement action against manufacturers that mislabel products as containing multiple servings when they are typically consumed in one eating occasion, in violation of §403(a) of the Federal Food, Drug, and Cosmetic Act ("the Act") 21 U.S.C §§301 et seq.;

(2) Initiate a rulemaking proceeding to revise the current regulations to reflect the dramatic changes in consumption patterns that have developed since they were issued 11 years ago (indeed, many RACCs were based on data published by USDA in 1982 and collected in the 1977-78 Nationwide Food Consumption Survey. Soft drinks and baked goods of sizes up to and including 300% of the reference amount currently consumed ("RACC") should be defined as single-serving products. Snack foods containing up to 400% of the RACC amounts should be labeled as single-serving products if the package is typically consumed by one person at one time. Snack foods containing between 200% and 400% of the RACC that may either be consumed at one time or as multiple portions should be required to include two columns to provide nutrition information on a per-serving and per-package basis. In addition, such packages should be required to bear the statement "contains \_\_\_\_ servings" on the Principal Display Panel.

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Executive Director

2004 P-0483

SUP1

Products in other categories, such as candy bars, dried soups, frozen entrees, pizza crusts, and fruit cups, also come in over-sized single-serving packages. The FDA should consider taking enforcement action against some of those products, too. Several major manufacturers voluntarily are beginning to provide information about the contents of entire packages, but the nature of that information is not always consistent. FDA regulations are needed to ensure that the serving-size information will be consistent and as clear as possible to consumers.

The basis for these recommendations is summarized below and explained in depth in the accompanying Petition for rulemaking on the nutrition labeling of foods and beverages sold in oversized single-serving containers.

## **I. Background**

Under existing regulations, manufacturers of products containing more than 200% of the RACC have the discretion to label such products as a single-serving “if the entire content of the package can reasonably be consumed at a single-eating occasion.”<sup>1</sup> However, the Preamble to FDA’s serving-size regulation limits that discretion in situations where the product is “obviously” intended to be consumed in one serving. The Preamble states:

regardless of the package size a product that is obviously intended to be consumed in one serving (e.g., one unit products in discrete units such as muffins, ice cream bars, and sandwiches; products bearing label descriptions that suggest a single serving such as “singles” or “the perfect size for one”) must be labeled as one serving. Otherwise, the labeling will be misleading under section 403(a) of the act.<sup>2</sup>

As will be explained in detail below, many soft drinks and snack foods are being sold in what are obviously single-serving containers but the containers are labeled as containing multiple servings. In addition, baked goods, such as muffins, that are sold in discrete units are also labeled as containing multiple servings. Clearly, such labeling violates Section 403(a) of the FDCA. That provision deems a product misbranded if “its labeling is false or misleading in any particular.” Large, single-serving packages that pretend to provide several servings are clearly misleading.

Instead of bringing enforcement actions, however, FDA did nothing for years, then simply encouraged “manufacturers to provide the most accurate and useful nutrition information to consumers by taking advantage of the flexibility in current regulations on serving sizes and label food packages as containing a single-serving if the entire contents of the package can reasonably be consumed at a single-eating occasion.”<sup>3</sup> That gives manufacturers a mixed

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<sup>1</sup> 21 C.F.R. § 101.9.

<sup>2</sup> 58 Fed. Reg. 2229, 2233 (Jan. 6, 1993).

<sup>3</sup> CFSAN/Office of Nutritional Products, Labeling and Dietary Supplements, *Letter to Food Manufacturers about Accurate Serving Size Declaration on Food Products*, (Mar. 12, 2004).

message by encouraging them to do one thing, but allowing them to do another. The seriousness of the obesity epidemic confronting this country calls for a stronger response by FDA.

Although FDA has publicly stated its intent to revise the Agency's serving size regulations, the notice and comment rulemaking process is a lengthy one. While such a proceeding is pending, many consumers will be misled into consuming extra calories. Therefore, FDA should take enforcement action promptly to prevent misleading labeling of large single-serving packages. FDA has the authority to take enforcement action at this time.

#### **A. New Evidence Overcomes FDA's Previous Objections to Imposing Single-Serving Requirements on Soft Drinks and Snacks**

FDA discussed the precise question of whether to require over-sized beverages and snacks to be labeled as single-serving products during its 1991-1993 rulemaking proceeding on serving sizes. At that time, FDA rejected such an approach, stating:

FDA does not believe that it is appropriate to change the definition of a single-serving container so that certain sizes of a selected class of products can be labeled as a single serving or to set a different requirement for a selected class of products without food consumption data or a scientifically sound basis that supports such a different requirement.<sup>4</sup>

FDA's previous objections to requiring that super-sized products be labeled as single servings are no longer relevant because new evidence demonstrates that super-sized products are widely consumed on single-eating occasions. In addition, as discussed in greater detail in Section II, major manufacturers of over-sized products refer to the fact that they are sold in single-serving containers on the packages themselves, in advertising or on their websites. Such products "are obviously intended to be consumed in one serving" and are in violation of Section 403(a) of the Act, as acknowledged by FDA in the Preamble to the serving-size regulation.

#### **B. Prior FDA Policy Conclusions in the 1993 Preamble Should Not Bar Enforcement Actions**

Some companies might argue that FDA's 1993 explanation as to why it was not requiring single-serving size designations for over-sized soft drinks and snacks constitutes a binding advisory opinion that prevents the Agency from taking enforcement action at this time.<sup>5</sup> However, FDA no longer considers advisory opinions to be binding in circumstances such as this one.

Prior to 1992, FDA's own rules prohibited the Agency from recommending "legal action against a person or product with respect to an action taken in conformity with an advisory

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<sup>4</sup> 58 Fed. Reg. at 2233.

<sup>5</sup> 21 C.F.R. § 10.85(d).

opinion which has not been amended or revoked.”<sup>6</sup> In 1992, however, FDA departed from that approach, citing a number of court cases that held “that the agency cannot be estopped from enforcing the law.”<sup>7</sup> FDA proposed the following language:

An advisory opinion represents the best advice of FDA on a matter at the time of its issuance. However, an advisory opinion does not bind the agency, and it does not create or confer any rights, privileges, or benefits for or on any person. FDA, may, in its discretion, recommend or initiate legal or administrative action against a person or product with respect to an action taken in conformity with an advisory opinion, provided that the legal or administrative action is consistent with applicable statutes and regulations.”<sup>8</sup>

Although the 1992 proposal has not been finalized, its Preamble, nevertheless, constitutes FDA’s latest policy on this point. Therefore, FDA should not refrain from taking enforcement action against manufacturers who misleadingly label over-sized products that are typically consumed at a single occasion. Sending warning letters to manufacturers of super-sized products that are labeled as containing multiple servings is fully appropriate under Section 403(a) of the Act. In addition, enforcement actions against products that are sold in containers obviously intended for a single serving do not represent any change in FDA’s policy since that approach was set forth in the 1993 Preamble.

Warning letters to several prominent companies, accompanied by product seizures, would send a strong signal to the entire industry that FDA treats misbranding of such packages as a serious issue. CSPI recommends that FDA initially target three categories of products that appear to be the worst offenders on the market: soft drinks, snack foods, and baked goods.

## **II. Soft Drinks and Other Beverages**

According to one recent vending-industry report, 20-ounce bottles became the leading single-serve configuration in convenience stores several years ago, and the vending industry, which caters to the individual consumer, continues to catch up to this trend.<sup>9</sup> Bottles displaced cans in vending machines for the seventh consecutive year in 2002, grabbing 44.9% of all cold-drink sales.<sup>10</sup> Yet, 16-, 20-, and 24-oz. bottles of beverages (soft drinks, milk-based drinks, juices, and fruit drinks), which have a reference amount of 8-oz. (240 ml), are frequently labeled as containing 2, 2.5, or 3 servings per container even though the packages are marketed and consumed as single servings.

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<sup>6</sup> 21 C.F.R. § 10.85(c). That provision, although still technically in effect, is no longer followed.

<sup>7</sup> 57 Fed. Reg. 47314, 42415 (Oct. 15, 1992).

<sup>8</sup> 57 Fed. Reg. at 47317.

<sup>9</sup> “2003 State of the Vending Industry Report,” *Automatic Merchandiser*, August 2003.  
<http://www.amonline.com/PDF/AutomSOV12003.pdf> (accessed July 28, 2004).

<sup>10</sup> *Id.*

In some cases, labeling or advertising indicates that products are intended to be consumed as a single serving. For example:

- Coca-Cola is sold in 24-oz. bottles that state on the label: "It's Big! For those who thirst for more." The label states that the product provides three 8-oz. servings.
- Pepsi advertises its Sierra Mist soft drink in a TV commercial that shows two soccer players fighting over the last 20-oz. bottle in the cooler, implying that one person would consume the whole bottle. The label indicates that the bottle provides 2.5 servings.
- Tropicana Products, Inc., tells customers on its website to "look for Tropicana Twister in 20-oz. single-serve bottles," but it lists the calorie content for just half the bottle on the nutrition label.<sup>11</sup>
- AriZona Beverages refers on its website to its 24-oz. can of iced tea as a "single serve" product while listing nutrition information for 8 ounces.<sup>12</sup>
- Welch Foods, Inc., declares on its website that each 16-oz. bottle of its single-serve juice line contains an individual serving while listing nutrition information for 8 ounces.<sup>13</sup>

Clearly, the labeling for those products is misleading.<sup>14</sup>

### III. Snack Foods

Snack foods, which include chips, popcorn, pretzels, and similar foods, have a reference amount of one ounce (28 g). Nevertheless, larger packages of snack foods that are likely to be consumed as a single serving have become increasingly prevalent. Salty-snack manufacturers introduced a category of larger snack bags called Large Single-Serve ("LSS") to the vending industry in 1994, which contributed to the "upsizing" trend in snack foods.<sup>15</sup>

Recognizing the need to improve the labeling of its snacks, Kraft Foods, Inc. plans to label packages that contain two to four servings (200% to 400% of RACC) as follows: Products typically consumed by one person at one time will be labeled as a single serving. If the product is sometimes consumed by one person, but usually by more than one person, Kraft will provide nutrition information for both the full package and per serving. Kraft will also state on the front

<sup>11</sup> See <http://www.tropicana.com/index.asp?id=134> (accessed July 17, 2004).

<sup>12</sup> See <http://www.arizonabev.com/csr/history.asp> (accessed July 17, 2004).

<sup>13</sup> See <http://www.welchs.com/products/singleserve.html> (accessed July 17, 2004).

<sup>14</sup> Coca-Cola recently announced that it would have dual-column labels on soft drinks >12 oz. and ≤ 20 oz. CSPI believes that it is inappropriate and confusing to list RACC nutrient values for products that are almost always consumed as one serving. Also, Coca-Cola apparently does not plan to label its 24 oz. bottles as single servings (or with dual-columns), even though those products are marketed as single servings. FDA action is needed to ensure that all companies use the same labeling system so as to minimize consumer deception.

<sup>15</sup> "Large-size candy: Can vending follow success of retail?" *Automatic Merchandiser*, May 2002.  
[http://www.amonline.com/new/article\\_archives.asp?action=details&magarticle\\_id=564](http://www.amonline.com/new/article_archives.asp?action=details&magarticle_id=564) (accessed July 29, 2004).

of the package how many servings the package contains.<sup>16</sup> Kraft has already begun distribution of "Ritz Chips" bearing nutrition facts based on both the RACC and the entire package.<sup>17</sup> Also, PepsiCo has said that it will improve the labeling of its over-sized single-serving packages.<sup>18</sup>

But, Kraft and Frito-Lay aside, many 2-oz., 3-oz., and 4-oz. packages produced by other companies that can reasonably be consumed at a single sitting are still being labeled as containing multiple servings. FDA regulations are needed to ensure that all snack foods are labeled in a useful, clear, and consistent manner.

#### **IV. Muffins and Similar Baked Goods**

Muffins, coffee cakes, doughnuts, Danishes, and other sweet baked goods have a reference amount of 55 g (2-oz.), but many individually packaged baked goods in convenience stores contain two to three times that amount. Despite FDA statements in the Preamble that it considers over-sized packages of muffins to be examples of products that should be labeled as containing a single serving, many manufacturers continue to label their baked goods and "on-the-go" packages as containing multiple servings.

For example:

- Otis Spunkmeyer Co. lists its 4-oz. muffin as providing two servings.
- Bon Appetit Bakery, which sells single-serve baked goods in many convenience stores, advertises its 5-oz. French Sweetie pastry as a "meal in itself" while labeling the item as two servings.<sup>19</sup>

The FDA should take enforcement action to stop such labeling.

#### **V. Conclusion**

CSPI believes that adoption of the recommendations listed above would enable the FDA to utilize its authority to strike a small blow against obesity in the most expedient fashion. FDA should require, not just encourage, companies to correct the misbranding of large single-serving containers and to label their products in the most accurate and informative manner to consumers.

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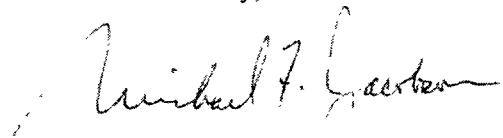
<sup>16</sup> See [http://www.kraft.com/responsibility/nhw\\_portionsizes.html](http://www.kraft.com/responsibility/nhw_portionsizes.html) (accessed October 1, 2004).

<sup>17</sup> Although the RACC for snack foods is 28g Kraft lists 29g as the serving size. We assume this is a typographical error.

<sup>18</sup> McKay B. "Coke and Pepsi plan to revise nutrition data on products." *Wall Street Journal*, October 20, 2004, p. B5.

<sup>19</sup> See <http://www.bonappetitbakery.com> (accessed July 15, 2004).

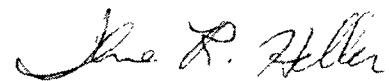
Sincerely,

A handwritten signature in cursive script, reading "Michael F. Jacobson".

Michael Jacobson, Ph.D.  
Executive Director

A handwritten signature in cursive script, reading "Bruce Silverglade".

Bruce Silverglade  
Director of Legal Affairs

A handwritten signature in cursive script, reading "Ilene R. Heller".

Ilene Ringel Heller  
Senior Staff Attorney

A handwritten signature in cursive script, reading "Emily Lee".

Emily Lee  
Legal Assistant

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

Petition for Rulemaking on Nutrition Labeling )  
for Food and Beverages Sold in Single-Serving )  
Containers )  
\_\_\_\_\_ )

Docket No. \_\_\_\_\_

Submitted by the

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

October 28, 2004

Michael F. Jacobson, Ph.D.  
Executive Director  
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1875 Connecticut Avenue, NW  
Washington, D.C. 20009  
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Dockets Management Branch  
United States Food and Drug Administration  
Department of Health and Human Services  
Room 1-23  
12420 Parklawn Drive  
Rockville, MD 20857

## **I. Introduction**

This petition requests action by the Food and Drug Administration ("FDA") to improve the nutrition labeling of single-serve packages of three categories of food and beverage products. This petition is submitted pursuant to sections 403(a), 403(q), and 701(a) of the Federal Food, Drug, and Cosmetic Act, section 4(e) of the Administrative Procedure Act, 5 U.S.C. §553(e), and 21 C.F.R. §§10.25 and 10.30.

The trend of increasing sizes of snack foods and beverages makes the current Nutrition Facts label on some products a misleading source of information for the average consumer. Numerous companies label certain single-serving products as containing multiple servings, contrary to §403(a) of the Federal Food, Drug and Cosmetic Act ("the Act").<sup>1</sup> Consumers are often led to believe that they are ingesting a fraction of the calories, fat, sodium, and cholesterol that the full-package serving actually contains. The Institute of Medicine of the National Academy of Sciences recently recommended that companies be required to more accurately label products that are consumed in a single serving.<sup>2</sup>

Under FDA's current regulatory scheme, as restated in its March 12, 2004, Letter to Food Manufacturers, manufacturers have the discretion to label over-sized products as either single or

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<sup>1</sup> 21 U.S.C. §343(a).

<sup>2</sup> "Preventing Childhood Obesity: Health in the Balance," National Academy of Sciences, Institute of Medicine, September 30, 2004.

multi-serving products. FDA's regulations must be revised to reflect realistic consumption patterns and to establish a more informative and less confusing labeling scheme for consumers.

## **II. Action Requested**

The Center for Science in the Public Interest ("CSPI") requests that the FDA promptly initiate rulemaking to change the definition of "single-serving container" within 21 C.F.R. §101.9(b)(6) for at least two categories of food products and adopt a new labeling scheme for snack foods.

- The cut-off for soft drinks/beverages and muffins/baked goods should be raised to include 300 % of the applicable "reference amount customarily consumed" ("RACC"). 21 C.F.R §101.9(b)(6) should be amended by adding an additional provision defining the new cut-off for the two categories: "For soft drinks/beverages and muffins/pastries, packages sold individually that contain up to and including 300% of the applicable reference amount must be labeled as a single serving." These packages would be labeled in the traditional format but would be required to list nutrition information for the entire package. Besides carbonated soft drinks, "beverages" should include bottled milk, fruit drinks, fruit juices, and other products.
- FDA should require manufacturers to label snack packages containing between 200% and up to and including 400% of the RACC as follows. If the product is usually consumed by one person, it should be labeled as a single-serving. If one person could consume the product, but the product is often consumed by multiple persons, the manufacturer should utilize dual-column labeling (labeling on a per-serving and per-package basis for the Nutrition Facts panel) and a front label declaring the number of (RACC) servings per package.

FDA should also consider whether cut-off levels for other categories of over-sized "single-serve" foods, such as candy bars, dried soups, frozen entrees, pizza crusts, and fruit cups, should be raised.

### **III. Statement of Factual Grounds**

#### **A. Despite FDA's Promulgation of Single-Serving Container Labeling Regulations in 1993, Misleadingly Labeled Products are Common in the Marketplace.**

Single-serving packages of soft drinks, snack foods, and individually-wrapped baked goods have increased in size since 1993. The 20-oz. bottle of soda is now a ubiquitous item in supermarkets, delis, convenience stores, and vending machines and is even defined as a "single-serve" container by the vending industry.<sup>3</sup> One packaging firm created the "Big Slam" 20-oz. bottle in response to Pepsi-Co's request for a "single-serve vessel that conveyed Pepsi values and the cola consumption experience."<sup>4</sup> Coca-Cola markets 24-ounce bottles for people who "thirst for more."

Increasing sizes of containers and larger serving sizes at restaurants have helped fuel increases in soft-drink consumption in the last 25 years.<sup>5</sup> Yet, 16-oz., 20-oz., and 24-oz. bottles are labeled as containing multiple servings. Current nutrition labeling may mislead consumers who might not understand that the serving labeled on the Nutrition Facts panel as containing 100 calories actually contains 250 calories if the entire bottle (which is labeled as containing 2.5 servings) is consumed at a single sitting.<sup>6</sup> Such labels also understate the amount of sugar

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<sup>3</sup> See "State of the Vending Industry Report 2003," *Automatic Merchandiser*, August 2003.

<sup>4</sup> See <http://www.webbscarlett.com/categories/nonalcoholicbeverages.race?product=pepsi> (accessed August 5, 2004).

<sup>5</sup> Nielsen SJ, Popkin BM. "Patterns and trends in food portion sizes, 1977-1998." *JAMA*. 2003 Jan 22;289(4):450-3. Portion sizes are probably larger than what is reported in the study because the last data was collected in 1998.

consumed at one sitting (and in the case of snack and baked foods, discussed below, the amounts of fat and sodium as well). Such labels thereby present a much better nutritional profile for the food than is actually the case.

Similarly, the introduction of Large Single-Serve ("LSS") snacks in 1994 contributed to the proliferation of increasingly large snack packages.<sup>7</sup> Bags of chips containing as much as 4.5 times the reference amount (1-oz.) for chips, are sold alongside 1-oz. bags at convenience stores, vending machines and by street vendors. It is clear that many consumers eat the entire contents of 2-oz., 3-oz., and 4 oz. bags (and those somewhere in between) at a single sitting or within a short period of time. One study reports that the average portion of salty snacks eaten at a single sitting increased from 1 ounce to 1.6 ounces between 1977-1998 and 1994-1996.<sup>8</sup> Again, portion sizes are probably larger now than what is reported in the study because the last data analyzed were collected almost 10 years ago. One vending industry newsletter reports that the average salty-snack consumption is over 2-oz. per eating occasion for vending machines because such machines are now a midday meal source."<sup>9</sup> Moreover, Kraft's decision, as discussed below, to provide dual-column labeling for snack packages and beverages that contain between 200% and 400% of the reference amount, and are generally consumed by more than one person,

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<sup>6</sup> Coca-Cola and PepsiCo have announced that they will use dual-column labeling on certain over-sized single-serving beverage containers. That represents some progress, but, voluntary labeling schemes by various companies likely will lead to inconsistencies and confusion.

<sup>7</sup> "Large-size candy: Can vending follow success of retail?" *Automatic Merchandiser*, May 2002.  
[http://www.amonline.com/new/article\\_archives.asp?action=details&magarticle\\_id=564](http://www.amonline.com/new/article_archives.asp?action=details&magarticle_id=564) (accessed July 29, 2004).  
See also "Brewing Bigger Profits" *APinsider*, Fall 2002.

<sup>8</sup> Nielsen SJ, Popkin BM. "Patterns and trends in food portion sizes, 1977-1998." *JAMA*. 2003 Jan 22;289(4):450-3.

<sup>9</sup> See [http://www.illinoisvending.com/pdf/winter\\_2002/15\\_winter\\_2002.pdf](http://www.illinoisvending.com/pdf/winter_2002/15_winter_2002.pdf) (accessed October 15, 2004).

reflects the obvious fact that many consumers eat entire super-sized bags of snacks at a single sitting.<sup>10</sup>

Jumbo-sized 4-oz. and 5-oz. muffins, popular items in convenience stores, continue to be labeled as containing multiple servings. Most people will consume an entire muffin or breakfast pastry at a time, especially when the package looks like it contains one serving.<sup>11</sup> FDA's Working Group on Obesity reported that when participants in their study were presented with a mock-up label of a 20-oz. soda and a large packaged muffin, they thought it was misleading to list either product as having more than one serving.<sup>12</sup>

Specific examples of over-sized "single-serving" products are given in our October 27, 2004, letter to the FDA, which we incorporate by reference into this Petition (Attachment A).

**B. Recent Scientific Evidence Suggests that Increased Soft-Drink Consumption Contributes Significantly to the Obesity Epidemic.**

Three recent studies link consumption of soft drinks with weight gain and obesity.<sup>13</sup> One study of school children found that the chances of becoming obese increased significantly with each additional daily serving of a sugar-sweetened drink.<sup>14</sup> The second found that the percentage

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<sup>10</sup> Kraft's labeling may be confusing because the number of grams or milligrams of nutrients for a single serving and the entire package are listed—separated by commas—just after the name of the nutrient. However, there is no explanation for why two numbers are given.

<sup>11</sup> FDA itself stated in the Preamble to 21 C.F.R. §101.9 that "one unit products in discrete units such as muffins" are examples of products that are obviously intended to be consumed in one serving. 58 Fed. Reg. at 2233.

<sup>12</sup> Food and Drug Administration, "Counting Calories – Report of the Working Group on Obesity." Section V.A.2. (March 12, 2004). See <http://vm.cfsan.fda.gov/~dms/owg-toc.html> (accessed October 19, 2004).

<sup>13</sup> Another study limited to snack foods consumed at one point in time, as opposed to changes over the course of time, as was done in the other studies found no correlation between snack food intake and weight change among children and teens. Field, AE, Austin SB et al, "Snack food intake does not predict weight change among children and adolescents." *Int. J. Obes. Metab Disord.* 2004 Oct; 28(10):1210-6. The usefulness of this study is limited as a result of the methodology used by its authors.

<sup>14</sup> Ludwig DS, Peterson KE, Gortmaker SL. "Relationship between consumption of sugar-sweetened drinks and childhood obesity: a prospective, observational analysis." *Lancet* 2001;357:505- 8.

of overweight and obese children decreased in a group that was encouraged to, and did, consume fewer soft drinks than a control group.<sup>15</sup> A third study correlated weight gain in adult women with increased consumption of soft drinks.<sup>16</sup> In addition, overall obesity rates have risen in tandem with national per capita soft-drink consumption, and heavy consumers of such products have higher calorie intakes.<sup>17</sup>

**C. Some Snack-Food and Soft-Drink Companies have Announced they will Label Some of Their Products in Accordance with Real Consumption Patterns.**

Not only do scientific evidence and consumption patterns support reforming single-serving labeling regulations, but one major snack-food company, Kraft, has recognized that more realistic labeling of single-serving products will “reflect changing perspectives on diet, activity and weight.”<sup>18</sup> For products sold in amounts equal to 200% to 400% of the RACC, Kraft will label the packages as follows. Products typically consumed by one person at one time will constitute a single serving. If a product is sometimes consumed by one person, but usually by more than one person, Kraft will provide nutrition information for both the full package and per serving. Kraft will also state the number of servings on the front of the package.<sup>19</sup> Thus, Kraft’s Ritz chips are labeled based on a serving size of 13 chips (29g) as well on the nutrition profile of the entire package. The front of the package states “About 2 Servings.”

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<sup>15</sup> James J, Thomas P, Cavan D, et al. “Preventing childhood obesity by reducing consumption of carbonated drinks: cluster randomized controlled trial.” *BMJ* 2004 April 27.

<sup>16</sup> Schultze MB, Manson JE, Ludwig DS, et. Al. “Sugar-sweetened beverages, weight gain, and incidence of type 2 diabetes in young and middle-aged women. *JAMA*. 2004;292:978-9.

<sup>17</sup> Analyses by Environ. Data on consumption of soft drinks, milk, and calorie intake were obtained or calculated from USDA surveys, including the Continuing Survey of Food Intakes of Individuals (CSFII), 1994-96; 1987-88; Nationwide Food Consumption Surveys, 1977-78. See USDA web site: [www.barc.usda.gov/bhnrc/foodsurvey/home.htm](http://www.barc.usda.gov/bhnrc/foodsurvey/home.htm) (accessed July 5, 2002).

<sup>18</sup> See [http://www.kraft.com/responsibility/nhw\\_healthypolicies.html](http://www.kraft.com/responsibility/nhw_healthypolicies.html) (accessed August 9, 2004). See footnote 10, *supra*, for CSPI’s concern about why Kraft’s approach might be confusing to consumers.

<sup>19</sup> See [http://www.kraft.com/responsibility/nhw\\_portionsizes.html](http://www.kraft.com/responsibility/nhw_portionsizes.html) (accessed October 1, 2004).

The combination of a principal display panel (PDP) disclosure and dual labeling on the Nutrition Facts Panel will alert consumers to snack foods that are high in calories and may prompt them to make better dietary choices. Kraft's efforts reflect only one company's move in the right direction, and FDA should require the rest of the food industry to label their over-sized single-serving products in a consistent and non-misleading way.

A second major company, Coca-Cola, announced that it would provide dual-column labeling on certain over-sized containers of soft drinks that it considers single servings.<sup>20</sup> However, the company has indicated that it does not plan to change the labeling of its 24-ounce bottles that are for people with a "big thirst." Furthermore, CSPI believes that it is disingenuous and misleading to use dual-column labeling on products that are marketed and consumed as single servings. News accounts indicate that a third large food processor, PepsiCo, will follow Coca-Cola's lead by changing the labeling of its beverages, as well as its Frito-Lay snack foods.<sup>21</sup>

A prominent maker of baked goods, Interstate Brands Companies (Hostess, Marie Callendar's, Dolly's, Drake's, Sunbeam, and others), is also moving toward dual-column labeling.<sup>22</sup> However, its labeling is slightly different from Kraft's. While Kraft shows the amounts of various nutrients for both the RACC servings and the whole package, as well as both %DVs (Daily Values), Interstate is giving the calories and %DVs for both serving sizes, but only the amounts of fat, sodium, and other nutrients for the RACC servings. Some people might

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<sup>20</sup> Coca-Cola news release, Oct. 15, 2004.

See [http://www2.coca-cola.com/presscenter/nr\\_20041015\\_expanded\\_nutrition\\_information.html](http://www2.coca-cola.com/presscenter/nr_20041015_expanded_nutrition_information.html) (accessed October 20, 2004).

<sup>21</sup> McKay B. "Coke and Pepsi plan to revise nutrition data on products." *Wall Street Journal*, October 20, 2004, p. B5.

<sup>22</sup> Telephone conversation between CSPI's Ann Bryant and an Interstate Brands customer-service representative, Oct. 22, 2004.

think that the numbers of milligrams and grams reflect the entire package, instead of one small serving.

Voluntary initiatives by individual companies are welcome, but CSPI fears that different companies will label their products in different ways, leading to labeling inconsistencies and consumer confusion. FDA regulations, based on focus groups and other research, would prevent those unintended, but perhaps inevitable, problems. In the Appendix, we present an alternative that shows the amounts and DVs of nutrients for both a RACC serving and the entire package.

#### **IV. Statement of Legal Grounds**

Our discussion of marketing data, scientific evidence, and consumer consumption patterns indicates that FDA must reform outdated single-serving labeling regulations to address the problem of misleading labels. Clearly, FDA has authority under the Act to require manufacturers to re-label their oversized single-serving products. Further, changed circumstances call for FDA to reconsider its position regarding dual-column labeling and front labels.

##### **A. Manufacturers Should Not be Permitted to Misleadingly Label their Products in Violation of §403(a).**

In a Letter to Food Manufacturers dated March 12, 2004, FDA stated that “current serving size regulations allow for [jumbo or over-sized] products to be sold as either one, or more than one, serving even if they are usually consumed at one time.” Although FDA encouraged manufacturers to label their over-sized products as single servings, many manufacturers will not re-label their products as long as FDA regulations (notwithstanding the Preamble), formally permit them to label them as containing more than one serving. Listing multiple servings results in unrealistically low levels of calories, fat, sugar, and other nutrients on



the Nutrition Facts panel and makes a large single-serving product appear more healthful than it really is.

As stated in our accompanying letter, the flexibility of 21 C.F.R. §101.9(b)(6), which (if the Preamble is ignored) permits some products that are reasonably consumed at one eating occasion to be labeled as containing multiple servings, should not continue to undermine the intent of Section 403(a) of the Federal Food, Drug, and Cosmetic Act (FDCA): Foods bearing labels that are false or misleading in any particular are misbranded.<sup>23</sup> The FDA explicitly stated in the Preamble to its serving size regulations:

regardless of the package size a product that is obviously intended to be consumed in one serving (e.g., one unit products in discrete units such as muffins, ice cream bars, and sandwiches; products bearing label descriptions that suggest a single serving such as “singles” or “the perfect size for one”) must be labeled as one serving. Otherwise, the labeling will be misleading under section 403(a) of the act.<sup>24</sup>

Revision of 21 C.F.R. §109(b)(6) to include certain over-sized products within the definition of “single-serving container” would prevent future injury by requiring food manufacturers to re-label those packages as containing a single serving.

**B. Raising the Single-Serving Category Cut-off to 300 Percent for Soft Drinks/Beverages and Baked Goods would Eliminate Loopholes and Confusion in the Existing Regulations.**

FDA regulations codified at 21 C.F.R. §101.9(b)(6) state that manufacturers *may* label products as a single serving if “the entire contents of the package can reasonably be consumed at a single-eating occasion.”<sup>25</sup> By adding a provision to 21 C.F.R. §101.9(b)(6) that raises the cut-

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<sup>23</sup> FDCA §343(a), 21 U.S.C. §403(a).

<sup>24</sup> 58 Fed. Reg. 2229, 2233 (Jan. 6, 1993).

<sup>25</sup> The relevant provision reads “Packages sold individually that contain 200 percent or more of the applicable reference amount may be labeled as a single-serving if the entire contents of the package can reasonably be

off to 300% for two of the most problematic food and beverage categories, FDA would make it clear that manufacturers must re-label their packages to avoid enforcement action.

In another development, the two largest soft-drink companies have announced plans to provide dual column Nutrition Facts panels on some of their beverage containers listing calorie and nutrient content for the entire package, as well as the reference amount customarily consumed. However, Coca-Cola's policy will not include its 24-ounce bottles that are clearly intended as single-serving products (for people who "thirst for more"). Also, it is disingenuous, inappropriate, and misleading to use dual-column labeling on a product that is normally not shared by 2.5 people. However, such labeling schemes adopted by various manufacturers will not be standardized and thus will likely be confusing to many consumers. The FDA needs to propose regulations to ensure that consistent information is provided in the marketplace.

**C. Raising the "Single-Serving" Cut-off to 300 Percent for Certain Products is Justified by Current Marketing Practices.**

As set forth above and in section II of our accompanying letter to the FDA, new consumption data, marketing evidence, and scientific studies linking soft drinks to obesity make it clear that FDA must act once again to address problems caused by the trend toward larger single-serving packages. Even though the FDA's 1993 Preamble specifically rejected a request to change the definition of a single-serving container so that larger sizes of a selected class of products would be required to be labeled as a single serving, that request did not present any food consumption data or other scientific basis, as we do in this Petition and accompanying letter, that would justify the suggested changes.<sup>26</sup> Moreover, marketing practices, consumption

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consumed at a single-eating occasion." 21 CFR §101.9(b)(6). Clearly, few companies have chosen to label oversized packages of high-calorie, low-nutrition foods as single servings.

<sup>26</sup> 58 Fed. Reg. 2233 (emphasis added).

patterns, and obesity levels have changed since 1993. Clearly, the 200% cut-off for soft drinks, muffins, and other baked goods is obsolete in light of current conditions.

**D. FDA Should Restate Its Position Regarding Dual-Column and Front Panel Labeling for Single-Serving Containers of Snack Foods.**

FDA should require manufacturers of snack foods containing up to and including 400% of the RACC to label their products as single-serving packages if the package is typically consumed by one person at one time. If, however, a product containing up to 400% of the RACC is arguably consumed either at one time by one person, or several occasions by the same person, or by multiple persons, the product should not be labeled solely as a single serving. Instead, such products should be required to bear labeling on a per-serving and a per-package basis, with an additional declaration on the PDP that the over-sized product may serve up to and including 4 persons.

**1) Dual-Columns on the Nutrition Facts Panel**

While the statute requires serving sizes to be based on the “amounts *customarily* consumed”<sup>27</sup> or “*other* units of measure,”<sup>28</sup> the quantity consumed often may be the whole package even though a “reasonable” (RACC) serving would constitute only a fraction of the package (emphasis added). In those cases, information should be provided on the Nutrition Facts panel for both the customary serving size and the entire package to make it easier for health-conscious consumers to make informed decisions about the amount consumed. The second column is permissible for Nutrition Facts based on consumption of the entire package under FDA’s authority to require the declaration of serving size in terms of “other units of measure.”

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<sup>27</sup> 21 U.S.C. §403(q)(A)(i) (emphasis added).

<sup>28</sup> 21 U.S.C. §403(q)(1)(B) (emphasis added).

FDA's 1993 rejection of a dual-column Nutrition Facts panel should be reconsidered in light of current marketing trends and consumption patterns. As the FDA's own Obesity Working Group Report concluded, comments should be solicited on "whether to require additional columns in the Nutrition Facts panel."<sup>29</sup>

FDA should not let concerns over space constraints prevent it from undertaking a rulemaking to adopt our suggested labeling scheme.<sup>30</sup> The typical, flat rectangular snack-food packages that would be affected by a 200% to 400% rule generally provide enough space to accommodate a second column of nutrition information based on the entire package. FDA already permits dual labeling for metric declarations,<sup>31</sup> for two or more forms of the same food -- e.g., both "as purchased" and "as prepared"<sup>32</sup> -- and products promoted for a use that differs in quantity by two-fold or greater from the use upon which the reference amount is based (e.g., liquid creamer substitutes promoted for use with breakfast cereals).<sup>33</sup> FDA should solicit comments from industry and the general public on the best way to format new labels and conduct appropriate consumer research.

## **2) Principal Display Panel Disclosure**

In addition, the FDA should require that manufacturers of products containing 200% to 400% of the RACC that are often not consumed by just one person to state on the PDP of packages "Serves \_\_\_\_\_," with the blank being filled in with a whole number indicating the

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<sup>29</sup> See note 12 *supra* at 5.A.3.

See <http://vm.cfsan.fda.gov/~dms/owg-qa.html> (accessed October 19, 2004).

<sup>30</sup> If labels are, indeed, too small for dual-column labeling, the FDA should require at least the calorie content of the entire package to be listed. Also, the Principal Display Panel should state "Contains \_\_\_\_\_ servings."

<sup>31</sup> 21 C.F.R. §101.9(b)(10).

<sup>32</sup> 21 C.F.R. §101.9(e).

<sup>33</sup> 21 C.F.R. §101.9(b).

customary number of RACC servings that could be provided. That statement on the PDP, together with a dual-column Nutrition Facts panel, would provide consumers with a useful comparison as to the number of calories, as well as the amounts of fat and other nutrients. Such action is appropriate in light of the fact that the FDA has failed to take enforcement action against misleading labeling of snack foods under §403(a), as it stated it would do in 1993 when it rejected comments favoring a PDP disclosure.<sup>34</sup>

## **VI. Conclusions and Recommendations**

Despite FDA's good intentions, consumers today are misled by labeling on larger-sized single-serving packages of beverages, snack foods and baked goods and still lack simplified, reliable information to gauge their intake of calories, fat, sodium, and cholesterol. FDA should reform obsolete and ambiguous labeling regulations and should, therefore, immediately initiate a rulemaking to revise the single-serve cutoffs as described above. The need for such a rulemaking is heightened by the voluntary labeling schemes being adopted by companies that could lead to inconsistent labeling and confusion in the marketplace.

## **VII. Environmental Impact**

The action requested is subject to a categorical exclusion under 21 C.F.R. §25.30(h) and therefore does not require the preparation of an environmental assessment.

## **VIII. Economic Impact**

No statement of the economic impact of the requested action is presented because none has been requested by the Commissioner.

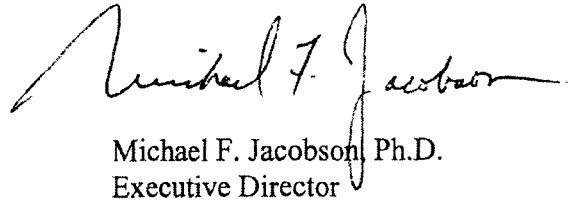
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<sup>34</sup> 58 Fed. Reg. 2229, 2235.

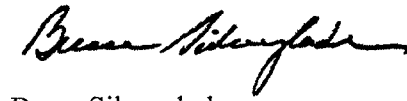
### IX. Certification

The undersigned certify that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the petition relies, and it includes representative data and information known to the petitioner which are unfavorable to the petition.

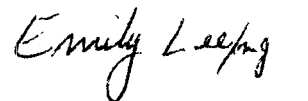
Respectfully submitted,



Michael F. Jacobson, Ph.D.  
Executive Director



Bruce Silverglade  
Director of Legal Affairs



Emily Lee  
Office of Legal Affairs

<b>Nutrition Facts</b>				
Serving size: 1 oz. Servings Per Package: 3.5			<b>Nutrients for Entire Package</b>	
	<b>Amount Per Serving</b>	<b>%Daily Value</b>	<b>Per Package</b>	<b>%Daily Value</b>
<b>Calories</b>	150		525	
<b>Total Fat</b>	9 g	14%	32 g	49%
Saturated Fat	2.5 g	13%	9 g	46%
<b>Cholesterol</b>	0 mg			
<b>Sodium</b>	260 mg	11%	910 mg	39%
<b>Total Carbohydrate</b>	16 g	5%	56 g	18%
Dietary Fiber	< 1 g	2%	2 g	7%
Sugars	< 1 g		2 g	
<b>Protein</b>	2 g	4%	7 g	14%
Vitamin A		10%		0%
Vitamin C		0%		0%
Calcium		0%		0%
Iron		0%		0%
*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.				